IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 09-037 (RBK)(JS) CONSOLIDATED
SHIONOGI, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. MYLAN, INC., and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 10-135 (RBK)(JS)

AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

For their complaint herein, Plaintiffs allege as follows:

1. Sciele Pharma, Inc. (now known as Shionogi Pharma Inc. ("Shionogi")) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive, Florham Park, New Jersey 07932.

2. Andrx Corporation ("Andrx Corp.") is a Delaware corporation and subsidiary of Watson Pharmaceuticals, Inc., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Pharmaceuticals, Inc. ("Andrx Pharmaceuticals") is a Florida corporation and subsidiary of Andrx Corp., now known as Watson Laboratories, Inc.-Florida, having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Pharmaceuticals, L.L.C. and Andrx Labs, L.L.C. are Delaware limited liability companies and subsidiaries of Andrx Corp., having a place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx Laboratories (NJ), Inc. is a Delaware corporation and a subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. Andrx EU Limited is a UK corporation and subsidiary of Andrx Corp., having a place of business at 8151 Peters Road, 4th Floor, Plantation, Florida 33324. The Andrx companies are hereinafter referred to collectively as "Andrx."

3. Defendant Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a Virginia corporation and a wholly-owned subsidiary of Defendant Lupin Ltd., having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Defendant Lupin Pharma manufactures, imports, sells, offers for sale and/or distributes generic drugs, manufactured by Defendant Lupin, Ltd., for sale and use throughout the United States, including in this judicial district.

4. Defendant Lupin Ltd. ("Lupin") is a corporation organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra

Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Defendant Lupin itself and through its wholly-owned subsidiary and agent Defendant Lupin Pharma, manufactures imports, sells, offers for sale and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

5. Defendants Lupin and Lupin Pharma sell generic drugs that are manufactured by Defendant Lupin, Ltd. throughout the U.S., including in this judicial district.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the facts that, *inter alia,* each of Lupin and Lupin Pharma has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Shionogi, a Delaware corporation. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below.

8. Lupin Pharma participated in the preparation and filing of Lupin's ANDA No. 90-692 as an agent of Lupin.

9. Lupin is in the business of developing, manufacturing, marketing, and selling generic drugs. On information and belief, Lupin established Lupin Pharma for the purpose of distributing, marketing, and selling its generic drug products in the United States. Lupin maintains an Internet website at the URL www.lupinworld.com at which Lupin represents that it has a representative office at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, the principal place of business of Lupin Pharma.

10. Upon information and belief, based in part on representations on their websites and Lupin's Annual Report, Lupin and Lupin Pharma hold themselves out as a unitary entity by representing to the public that the activities of Lupin and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin, headquartered in India.

11. Upon information and belief, Lupin maintains and controls a broad distribution network in the United States for Lupin's products that results in the distribution and sale of hundreds of millions of dollars of Lupin's products. The distribution network includes its "direct to market team" and its "structure for marketing generic products," as well as several marketing alliances with other companies in the United States.

12. Upon information and belief, based in part on the representations on their websites, Lupin and Lupin Pharma sell Lupin drug products directly to Amerisource Bergen, Cardinal Health, and Walgreens, who then sell Lupin's drug products throughout the United States, including in this judicial district.

13. Upon information and belief, based in part on the representation on Lupin and Lupin Pharma's websites, Lupin Pharma has, since at least December 20, 2005, maintained as an authorized distributor of record for Lupin's generic drugs a company located within this judicial district, Happy Harry's, a Walgreen's pharmacy, 326 Ruthar Dr., Newark, Delaware 19711. Upon information and belief, Happy Harry's was Delaware's largest drug store chain.

14. Upon information and belief, Lupin is currently the sole manufacturer of the "Suprax®" drug product in the United States, and Lupin Pharma distributes "Suprax®" for sale throughout the United States, including in this judicial district. Upon further information and belief, the package insert for the "Suprax®" drug product manufactured by Lupin and sold

throughout the United States, including in this judicial district, states that the "Suprax®" drug product is manufactured for Lupin Pharma.

15. Upon information and belief, Lupin has entered into a multi-year contract with Forest Laboratories, Inc., a Delaware corporation, to promote the "AeroChamber Plus®" drug product, whereby Lupin Pharma has used its "50 person sales force to promote the product to pediatricians." Upon information and belief, Lupin Pharma distributes the "AeroChamber Plus®" drug product for sale throughout the United States, including in this judicial district.

16. This Court has personal jurisdiction over Defendant Lupin Pharma by virtue of, *inter alia,* its systematic and continuous contacts with Delaware.

17. This Court has personal jurisdiction over Defendant Lupin by virtue of, *inter alia,* its systematic and continuous contacts with Delaware.

PATENTS IN SUIT

18. Andrx is the owner of United States Patent No. 6,099,859 ("the '859 patent"), which was duly and legally issued on August 8, 2000, and is titled "Controlled Release Oral Tablet Having A Unitary Core." Shionogi has an exclusive license under the '859 patent in the United States. A copy of the '859 patent is attached as Exhibit A.

19. Andrx is the owner of United States Patent No. 6,866,866 ("the '866 patent"), which was duly and legally issued on March 15, 2005, and is titled "Controlled Release Metformin Compositions." Shionogi has an exclusive license under the '866 patent in the United States. A copy of the '866 patent is attached as Exhibit B.

ACTS GIVING RISE TO THIS ACTION

20. Andrx Labs is the holder of New Drug Application ("NDA") No. 21-574, by which the United States Food and Drug Administration ("FDA") granted approval for 500 mg and 1000 mg extended-release metformin hydrochloride tablets. The metformin hydrochloride

tablets described in Andrx's NDA are indicated as an adjunct to diet and exercise to lower blood glucose to improve glycemic control in adults with Type 2 diabetes mellitus. Shionogi markets these tablets in the United States under the tradename "Fortamet®."

21. Lupin submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-692, which included a certification with respect to the '859 and '866 patents under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to manufacture, use, and sell 500 mg and 1000 mg extended-release metformin hydrochloride tablets ("the ANDA products") prior to the expiration of those patents.

22. On or about December 3, 2008, Lupin sent a letter ("Notice Letter") to Watson Pharmaceuticals, Inc., and Andrx in which Lupin represented that it had filed an ANDA for the ANDA products, including certifications with respect to the '859 and '866 patents, and that it sought approval of its ANDA prior to the expiration of those patents.

23. On June 29, 2011, the FDA approved Lupin's ANDA.

24. Prior to about September 30, 2011, Lupin and Lupin Pharma imported into the United States, offered for sale, and sold, a substantial quantity of their generic version of FORTAMET. This "stealth" importation utilized covert means to prevent detection or disruption.

25. On or about September 30, 2011, Lupin and Lupin Pharma engaged in a "stealth" launch of their generic version of FORTAMET, offering for sale, selling, distributing, and/or shipping a substantial quantity of its generic version of FORTAMET.

26. Shionogi filed a motion for preliminary injunction against Lupin on October 12, 2011. (D.I. 205).

27. On December 6, 2011, the Court granted Shionogi's motion for preliminary injunction, finding that Shionogi had demonstrated a likelihood of success on the merits against Lupin. (D.I. 279).

28. Upon information and belief, Lupin and Lupin Pharma have not recalled their generic version of FORTAMET from the marketplace.

29. Upon information and belief, Lupin and Lupin Pharma's generic version of FORTAMET continues to be sold in the marketplace.

FIRST COUNT FOR INFRINGEMENT UNDER 35 U.S.C. § 271(e)
BY LUPIN AND LUPIN PHARMA OF UNITED STATES PATENT NO. 6,099,859

30. Plaintiffs reallege paragraphs 1-29 as if fully set forth herein.

31. Because Lupin and Lupin Pharma sought approval of ANDA No. 90-692 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '859 patent before its expiration, Lupin and Lupin Pharma have infringed the '859 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, the commercial manufacture, use, offer to sell, sale or import of the Lupin products that are the subject of ANDA No. 90-692 would infringe the '859 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA be a date that is not earlier than the expiration date of the '859 patent, or any later expiration of exclusivity for the '859 patent to which Plaintiffs are or become entitled.

33. Lupin's and Lupin Pharma's infringement of the '859 patent was and is willful and deliberate.

34. Lupin and Lupin Pharma were aware of the existence of the '859 patent and were aware that the submission of the ANDA and certification with respect to the '859 patent constituted an act of infringement of that patent.

35. This case is an exceptional one and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

SECOND COUNT FOR INFRINGEMENT UNDER 35 U.S.C. § 271(e) BY LUPIN AND LUPIN PHARMA OF UNITED STATES PATENT NO. 6,866,866

36. Plaintiffs reallege paragraphs 1- 35 as if fully set forth herein.

37. Because Lupin and Lupin Pharma sought approval of ANDA No. 90-692 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '866 patent before its expiration, Lupin and Lupin Pharma have infringed the '866 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, the commercial manufacture, use, offer to sell, sale or import of the Lupin products that are the subjects of ANDA No. 90-692 would infringe the '866 patent. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Lupin's ANDA be a date that is not earlier than the expiration date of the '866 patent, or any later expiration of exclusivity for the '866 patent to which Plaintiffs are or become entitled.

39. Lupin's and Lupin Pharma's infringement of the '866 patent was and is willful and deliberate.

40. Lupin and Lupin Pharma were aware of the existence of the '866 patent and were aware that the filing of the ANDA and certification with respect to the '866 patent constituted an act of infringement of that patent.

41. This case is an exceptional one and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

THIRD COUNT FOR INFRINGEMENT BY LUPIN AND LUPIN PHARMA UNDER 35 U.S.C. § 271(a)-(c) OF UNITED STATES PATENT NO. 6,099,859

42. Plaintiffs reallege paragraphs 1- 41 as if fully set forth herein.

43. Lupin and Lupin Pharma have actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-692 to the FDA. Lupin and Lupin Pharma were aware of the '859 patent when they engaged in these knowing and purposeful activities referred to above.

44. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Lupin Pharma induced the infringement of the '859 patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 90-692. The filing of the ANDA by Lupin and Lupin Pharma constitutes a direct act of infringement under 35 U.S.C. §271(e). Lupin Pharma's active and knowing aiding and abetting Lupin in the filing of ANDA No. 90-692 constitutes induced infringement.

45. Under 35 U.S.C. §§ 271(a)-(c), Lupin and Lupin Pharma have without authority manufactured, used, offered to sell, sold, or imported their generic version of FORTAMET, and therefore have infringed, and are still infringing, the '859 patent.

46. Lupin and Lupin Pharma have infringed and continue to infringe the '859 patent directly, contributorily, and/or by inducement, in violation of 35 U.S.C. § 271.

47. Lupin's and Lupin Pharma's infringement of the '859 patent has caused and will continue to cause Plaintiffs irreparable harm, for which there is no adequate remedy at law, unless Lupin's and Lupin Pharma's infringing activities continue to be enjoined.

48. Under 35 U.S.C. § 284, Lupin and Lupin Pharma are liable for damages to Plaintiffs, in an amount to be determined at trial, for injury to Plaintiffs caused by Lupin's and Lupin Pharma's infringement of the '859 patent.

49. Lupin's and Lupin Pharma's infringement of the '859 patent was and is willful and deliberate.

50. This case is an exceptional one and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

FOURTH COUNT FOR INFRINGEMENT BY LUPIN AND LUPIN PHARMA UNDER 35 U.S.C. § 271(a)-(c) OF UNITED STATES PATENT NO. 6,866,866

51. Plaintiffs reallege paragraphs 1- 50 as if fully set forth herein.

52. Lupin and Lupin Pharma have actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 90-692 to the FDA. Lupin and Lupin Pharma were aware of the '866 patent when they engaged in these knowing and purposeful activities referred to above.

53. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Lupin Pharma induced the infringement of the '866 patent by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 90-692. The filing of the ANDA by Lupin and Lupin Pharma constitutes a direct act of infringement under 35 U.S.C. §271(e). Lupin Pharma's active and knowing aiding and abetting Lupin in the filing of ANDA No. 90-692 constitutes induced infringement.

54. Under 35 U.S.C. §§ 271(a)-(c), Lupin and Lupin Pharma have without authority manufactured, used, offered to sell, sold, or imported their generic version of FORTAMET, and therefore have infringed, and are still infringing, the '866 patent.

55. Lupin and Lupin Pharma have infringed and continue to infringe the '866 patent directly, contributorily, and/or by inducement, in violation of 35 U.S.C. § 271.

56. Lupin's and Lupin Pharma's infringement of the '859 patent has caused and will continue to cause Plaintiffs irreparable harm, for which there is no adequate remedy at law, unless Lupin's and Lupin Pharma's infringing activities continue to be enjoined.

57. Under 35 U.S.C. § 284, Lupin and Lupin Pharma are liable for damages to Plaintiffs, in an amount to be determined at trial, for injury to Plaintiffs caused by Lupin's and Lupin Pharma's infringement of the '866 patent.

58. Lupin's and Lupin Pharma's infringement of the '866 patent was and is willful and deliberate.

59. This case is an exceptional one and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

60. Plaintiffs request that:

a. Judgment be entered that Defendants have infringed the '859 and '866 patents by submitting the aforesaid ANDA, and by making, using, offering to sell, selling, and/or importing into the United States their generic version of FORTAMET;

b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '859 and '866 patents.

c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 90-692 be a date that is not earlier than the expiration date of the '859 and '866 patents, or any later expiration of exclusivity for the '859 and '866 patents to which Plaintiffs are or become entitled;

d. Judgment that Defendants' infringement of the '859 and '866 patents was and is willful and deliberate.

e. Judgment awarding Plaintiffs damages adequate to compensate them for the harm caused by Defendants' infringement, which this Court should treble pursuant to 35 U.S.C. § 284.

f. Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285; and

g. They be granted such other and further relief as the Court may deem just and proper under the circumstances.

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